TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Economic Impact Statement

LSA Document #11-102

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

1. Description of Rule:

The health care-associated infection reporting rule will require hospitals licensed by the Indiana State Department of Health (ISDH) to report information on five of the six health care-associated infections targeted by the Centers for Disease Control and Prevention (CDC). Ventilator-associated pneumonia will not be included because there are not clear clinical definitions established and approved by the CDC. The reporting will be done through a web based system created and managed by the CDC known as the National Healthcare Safety Network (NHSN). The NHSN has become the national standard for infection reporting and the one used by hospitals that wish to receive higher medicare reimbursement. Each hospital will be required to enroll in the NHSN and confer rights to the ISDH for access to the nonidentifying information that they enter on health care-associated infections.

2. Description of the Affected Industry

This rule will affect 148 hospitals licensed under <u>IC 16-21</u> by the ISDH. Of those 148, approximately seven may meet the definition of a small business found at <u>IC 5-28-2-6</u>. This excludes state, mental health, and psychiatric hospitals.

3. Reporting, Record Keeping, and Other Administrative Costs

410 IAC 15-1.4-2 requires hospitals to have quality assessment and improvement programs, which include the area of infection control. Quality assessment and improvement programs should include monitoring and tracking of infections currently. Some of the hospitals that meet the definition of a small business may have to increase their monitoring and tracking and data entry time if they are not currently monitoring and tracking for all six health care-associated infections.

4. Estimated Total Annual Economic Impact on Small Businesses

This proposed rule will impose requirements on about seven small businesses in the form of increased hours for monitoring and tracking health care-associated infections and the subsequent data entry in the NHSN. Those meeting the definition of a small business should not see a substantial increase in costs because they have to meet 410 IAC 15-1.4-2 already.

5. Justification for Costs

This rule is intended to promote and protect the public safety and health. Health care-associated infections are the most common complication of hospital care and are one of the top 10 leading causes of death in the United States, accounting for an estimated 1.7 million infections and 99,000 associated deaths in 2002. The financial burden attributable to these infections is estimated at \$28 to \$33 billion in excess health care costs each year. The extent of the impact on Indiana is not precisely known as data has never been collected and shared except within individual hospitals. Data on Clostridium difficile infections comes from the Association of Professionals in Infection Control and Epidemiology (APIC) who contracted with Jason and Jarvis Associates to conduct a national prevalence study of Clostridium difficile. 648 facilities, mostly acute care hospitals, participated representing 47 states. The data included both colonized and infected. Facilities were to take one day during the month and report on their Clostridium difficile incidents for that day. Data showed that 13 out of every 1,000 inpatients in the survey were either infected (94.4%) or colonized (5.6%). This was 6.5 to 20 times previous estimates. Hospital discharge data from Indiana shows a dramatic increase in Clostridium difficile deaths from 2002 to 2006. No information is available from Indiana on infection rates. Reporting of health care-associated infections through this rule will provide the data from hospitals to identify the rates and infection problem areas, help provide the focus for remedial and preventative actions to improve infection control, and inform the public about infection rates. Reporting increases accountability and transparency. Data on health care-associated infections can drive focused prevention initiatives. When data establishes where infections are occurring, prevention efforts can be aimed at the problem infection areas to protect patients.

6. Regulatory Flexibility Analysis

Health care-associated infections are an increasing problem threatening the health and safety of patients not only in Indiana, but nationwide. While this problem has not been ignored by health care facilities, it is clear from the data that is available that the problem is not decreasing. More attention and resources must be brought to bear to address the situation. In Las Vegas in February 2008, ambulatory surgical centers were found to have been reusing syringes, saving money on supplies. Over 40,000 persons in the Las Vegas area were exposed to

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communicable diseases as a result. This is one example of how the market has not regulated itself when it comes to infection control and cost savings. Hospitals have not voluntarily made their infection rates available to the public. In fact, when offered the opportunity to join the voluntary Indiana Health Care-Associated Infection Initiative, many hospitals declined to join when they learned that their infection rates could become public. The reporting requirements fit the situation no matter the size of the hospital. The reporting required through the NHSN will be based on the number of patients and the number of health care-associated infections that occur at the facility. Other reporting options would require additional software costs or duplication of data entry for hospitals covered by this proposed rule.

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